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| APPLICATION NO.                                      | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO |
|--|-----------------|----------------------|-------------------------|-----------------|
| 09/698,121   | 10/30/2000      | Jerome Aucouturier   | 746200-000062           | 5877            |
| 21967  | 7590 02/17/2006 |                      | EXAMINER                |                 |
|  | & WILLIAMS LLP  | EWOLDT, GERALD R     |                         |                 |
| INTELLECTUAL PROPERTY DEPARTMENT 1900 K STREET, N.W. |                 |                      | ART UNIT                | PAPER NUMBER    |
| SUITE 1200   |                 |                      | 1644                    |                 |
| WASHINGTON, DC 20006-1109                            |                 |                      | DATE MAILED: 02/17/2006 |                 |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.   | Applicant(s)   |  |  |  |  |
|---|---|--|--|--|--|--|
|   | 09/698,121  | AUCOUTURIER ET AL.   |  |  |  |  |
| Office Action Summary   | Examiner  | Art Unit   |  |  |  |  |
|   | G. R. Ewoldt, Ph.D.   | 1644   |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |   |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period versilure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). |  |  |  |  |
| Status  |   |  |  |  |  |  |
| 1)⊠ Responsive to communication(s) filed on   |   |  |  |  |  |  |
|   | action is non-final.  | ,  |  |  |  |  |
| <u> </u>  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is   |  |  |  |  |  |
|   | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.   |  |  |  |  |  |
| Disposition of Claims   |   |  |  |  |  |  |
| 4) Claim(s) is/are pending in the application   | 4) Claim(s) is/are pending in the application.  |  |  |  |  |  |
|   | 4a) Of the above claim(s) is/are withdrawn from consideration.  |  |  |  |  |  |
| ) ☐ Claim(s) is/are allowed.  |   |  |  |  |  |  |
| Claim(s) is/are rejected.   |   |  |  |  |  |  |
| 7) Claim(s) is/are objected to.   |   |  |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or   | election requirement.   |  |  |  |  |  |
| Application Papers  | ·   |  |  |  |  |  |
| 9)☐ The specification is objected to by the Examiner.   |   |  |  |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.   |   |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |   |  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  |   |  |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |   |  |  |  |  |  |
| Priority under 35 U.S.C. § 119  |   |  |  |  |  |  |
|   |   |  |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:  |   |  |  |  |  |  |
| 1.☐ Certified copies of the priority documents have been received.  |   |  |  |  |  |  |
|   | 2. Certified copies of the priority documents have been received in Application No  |  |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in Application No  |   |  |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).   |   |  |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.  |   |  |  |  |  |  |
|   |   | <b>-</b> .   |  |  |  |  |
|   |   |  |  |  |  |  |
| Mash  |   |  |  |  |  |  |
| Attachment(s)   | ,, CT   |  |  |  |  |  |
| 1) X Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date  |   |  |  |  |  |  |
| B) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  | 5) Notice of Informal Pa  |  |  |  |  |  |
| Paper No(s)/Mail Date   | 6) Other:   |  |  |  |  |  |

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## DETAILED ACTION

- 1. Applicant's remarks, filed 12/02/05, are acknowledged.
- 2. Claims 19, 20, 30, 31, and 33 are pending and being acted upon.
- 3. Applicant has requested that as U.S. Patent Application 08/946,114 be considered.

The application has been considered.

- 4. It is apparent that the wrong "'149" patent was applied as prior art in the previous action. Accordingly, the previous rejection has been withdrawn. A new rejection follows.
- 5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- e) the invention was described in-
- (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).
- 6. Claims 19, 20, 30, 31, and 33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 6,274,149.

The '149 patent teaches a method providing an adjuvant effect to a vaccine comprising at least one antigen or at least one in vivo generator of a compound comprising an amino acid sequence comprising combining said antigen or in vivo generator with a surfactant or with a mixture of surfactants, said surfactant or mixture of surfactants having an overall HLB number of between 5 and 15, wherein said vaccine is suitable for application mucosally, orally, nasally, rectally or vaginally. (see particularly, column 3 and Table 1, MONTANIDE). Note that the chosen species, mannitan oleate, is also disclosed in the

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Chemical Abstracts Registry file as mannide oleate. The reference further teaches that the composition may be polyethoxylated (column 4, line 25), modified with ethylene oxide (column 4, line 48), or ethoxylated (column 4, line 53).

The reference clearly anticipates the claimed invention.

- 7. No claim is allowed.
- 8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.
- 9. Please Note: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

G.R. Ewoldt, Ph.D. Primary Examiner

Technology Center 1600